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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,702	07/31/2001	Nissim Benvenisty	1822/113	3581

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BROMBERG & SUNSTEIN LLP
125 SUMMER STREET
BOSTON, MA 02110-1618

EXAMINER
CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/918,702	Applicant(s) BENVENISTY, NISSIM	
	Examiner Deborah Crouch	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-47 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 drawn to a method of mapping a pathway of differentiation of a population of embryonic cells, classified in class 435, subclass 375.

II. Claims 8-17, drawn to a method of directing differentiation of human embryonic cells to a specific cell type, classified in class 424, subclass 9.1.

III. Claims 18-20 and 35-37, drawn to a method of treating a subject suffering from a heart condition associated with degeneration of heart muscle comprising placing an effective amount of differentiated cells into the subject, classified in class 424, subclass 93.1.

IV. Claims 18, 21, 22 and 35-37, drawn to a method of treating a subject suffering from a kidney condition associated with degeneration of kidney tissue comprising placing an effective amount of differentiated cells into the subject, classified in class 424, subclass 93.1.

V. Claims 18, 23, 24 and 35-37, drawn to a method of treating a subject suffering from a skin condition associated with degeneration of skin tissue comprising placing an effective amount of differentiated cells into the subject, classified in class 424, subclass 93.1.

VI. Claims 18, 25, 26 and 35-37, drawn to a method of treating a subject suffering from a liver condition associated with degeneration of liver tissue comprising placing an effective amount of differentiated cells into the subject, classified in class 424, subclass 93.1. III.

VII. Claims 18, 27, 28 and 35-37, drawn to a method of treating a subject suffering from a brain condition associated with degeneration of brain tissue comprising placing an effective amount of differentiated cells into the subject, classified in class 424, subclass 93.1.

VIII. Claims 18, 29, 30 and 35-37, drawn to a method of treating a subject suffering from a spinal cord injury condition associated with degeneration of neurons comprising placing an effective amount of differentiated cells into the subject, classified in class 424, subclass 93.1.

IX. Claims 18, 31, 32 and 35-37, drawn to a method of treating a subject suffering from anemia associated with degeneration of cells or malfunction of cells comprising placing an effective amount of differentiated cells into the subject, classified in class 424, subclass 93.1.

X. Claims 18, 31, 32 and 35-37, drawn to a method of treating a subject suffering from immunodeficiency disease associated with degeneration of cells or malfunction of cells comprising placing an effective amount of differentiated cells into the subject, classified in class 424, subclass 93.1.

XI. Claims 18, 33, 34 and 35-37, drawn to a method of treating a subject suffering from an adrenal condition associated with degeneration of adrenal tissue comprising placing an effective amount of differentiated cells into the subject, classified in class 424, subclass 93.1.

XII. Claims 38-40 and 42-46, drawn to a kit for determining differentiation pathways where the kit is comprised of DNA primers, classified in class 536, subclass 24.2.
Claims 38-40 and 42-46, drawn to a kit for determining differentiation pathways where the kit is comprised of antibodies, classified in class 530, subclass 387.1.

XIII. Claim 41, drawn to a method for screening an endogenous factor to determine whether the factor is capable of causing directed differentiation in a population of human embryonic stem cells, classified in 435, subclass 377.

The inventions are distinct, each from the other because:

Inventions I and II are mutually exclusive and independent methods. Inventions I is drawn to a method of mapping a pathway of differentiation in embryonic cells. Invention II is drawn to a method of directing differentiation of human embryonic stem cells. Each invention requires materially different and separate protocols for implementation. Invention I requires that the steps in the differentiation pathway be monitored and detected. Invention II requires that embryonic stem cells be directed along a particular path to a particular cells type. Further, invention I is not needed for invention II and vice-versa.

Inventions I and any of inventions III-XI are mutually exclusive methods. Invention I, to methods of mapping a differentiation pathway, are not need to implement any of inventions III-XI, to methods of treating various diseases and conditions by implantation of a differentiated cell.

Inventions I and XII are distinct. Invention I, to methods of mapping a differentiation pathway can be analyzed using other detection means, such as by microscopic analysis. The kit and panel of invention XII can be used to direct differentiation.

Inventions I and XIII are drawn to mutually exclusive and independent methods. Inventions I is drawn to a method of mapping a pathway of differentiation in embryonic cells. Invention XIII is drawn to a method for screening an endogenous factor to determine if the factor causes directed differentiation in human embryonic stem cells. Each invention requires materially different and separate protocols for implementation. Invention I requires that the steps in the differentiation pathway be monitored and detected. Invention XIII requires that embryonic stem cells be analyzed for the presence of receptors. Also, invention I is not needed for invention XIII and vice-versa.

Inventions II and any of inventions III-XI are mutually exclusive methods. Invention II, methods of directing differentiation of human embryonic cells to a specific cell type, are not need to implement any of inventions III-XI, to methods of treating various diseases and conditions by implantation of a differentiated cell.

II and XII are distinct. Invention II, methods of directing differentiation of human embryonic cells to a specific cell type, can be detected such as by microscopic analysis. The kit and panel of invention XII can be used to map differentiation pathways.

Inventions II and XIII are drawn to mutually exclusive and independent methods. Invention II is to methods of directing differentiation of human embryonic cells to a specific cell type. Invention XIII is to a method for screening an endogenous factor to determine if the factor causes directed differentiation in human embryonic stem cells. Each invention requires materially different and separate protocols for implementation. Invention II requires that embryonic stem cells be differentiated into particular cell

types. Invention XIII requires that embryonic stem cells be analyzed for the presence of receptors. Also, invention II is not needed for invention XIII and vice-versa.

Inventions III-XI are mutually exclusive and independent methods. Each of inventions III-IX require the treatment of materially different and separate diseases with materially different and separate differentiated cells. Further, none of inventions III-XI are required for the implementation of each other.

Inventions III-XI and XII are mutually exclusive and independent methods. Inventions III-IX are to methods of treating various diseases and conditions by implanting a differentiated cell. Invention XII is to a kit and a panel of cell differentiation markers. Inventions II-IX and XII require materially different and separate protocols. Further, neither of the methods is required to implement any of the other methods.

Inventions III-XI and XIII are drawn to mutually exclusive and independent methods. Inventions III-IX are to methods of treating various diseases and conditions by implanting a differentiated cell. Invention XIII is to a method for screening an endogenous factor to determine if the factor causes directed differentiation in human embryonic stem cells. Each invention requires materially different and separate protocols for implementation. Also, none of inventions III-IX is needed for invention XIII and vice-versa.

Inventions XII and XIII are mutually exclusive and independent. Invention XII is to a kit and a panel of cell differentiation markers. Invention XIII is to a method for screening an endogenous factor to determine if the factor causes directed differentiation in human embryonic stem cells. Invention XII is not required for the implementation of invention XIII, and vice-versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of Claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126. The examiner's SPE is Deborah Reynolds, whose telephone number is (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Art Unit Patent Analyst, Ms. Pauline Farrier, whose telephone number is (703) 305-3550.

The fax number is (703) 308-4242.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630

Dr. D. Crouch
September 27, 2002